

Food and Drug Administration
5630 Fishers Land, Room 1061
Rockville, MD 20857-0003

19 May 1999

ATTN: Dockets Management Branch (HFA-305)

RE: DOCKET NO. 98N-1265

6248 99 MAY 24 A11:46

PLEASE STOP the proposed MOU to your Modernization Act of 1997.

This move will increase the risk of breast cancer for thousands of women, including me. This is NOT an exaggeration! My concern relates specifically to the area of women's health issues that are treated with ESTROGEN and PROGESTERONE.

- Most ESTROGEN has the potential for increasing the chance of breast cancer.
- Traditional PROGESTERONE is toxic to thousands of women, including me. I suffering from nausea, extreme fatigue and severe leg cramps each time I use it.

Since these drugs are vital to women, thousands of us have to:

- Swallow the chemicals provided through traditional pharmacies, OR
- Use the healthier, more gentle and "free from side affects" products available from pharmacies who are skilled enough to compound medications. They offer women:
- An estrogen which includes a known anti-cancer form of estrogen. No chemically-based pharmaceutical firms offer this combination.
- A food-based form of progesterone, which has no toxic side affects. No chemically-based pharmaceutical firms offer this product.


Your MOU would deprive thousands of women of these healthier medications, forcing them to return to the "traditional" drugs which are life threatening and/or toxic.

The Compounding Section 503A of your Modernization Act of 1997 already restricts my personal freedom to purchase health care products from the Pharmacy of my choice. Now, this MOU allows you to push yourself even deeper into my personal health care. You want me to buy my compounded medicines ONLY from pharmacies in my home state. Guess what? Texas doesn't HAVE any compounding pharmacies. So where does that leave me?

I look to you to be a "watch dog" for consumer safety. THIS IS NOT A SAFETY ISSUE. What possible reason could there be for me to be restricted from purchasing out of state medications? That eliminates mail order catalogs (which are cheaper) ... the Internet (which usually offers a better selection) ... etc. What right do you have to do that to the thousands of women who currently use out-of-state compounding pharmacies?

Instead of pushing into the WHERE of my medical purchases, why don't you look into the WHAT. The FDA could be a moving force in the fight against breast cancer by simply exploring the more non-traditional forms of hormones on the market.

If the head of the FDA had to go through menopause, this whole issue would be mute!


HELEN BALL
2330 Nashwood Drive
San Antonio, TX 78232

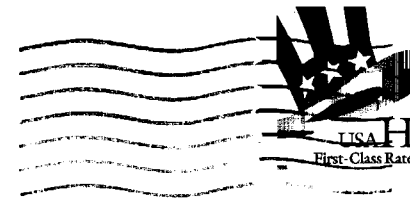
98N-1265

C 2615

RE:


Docket # 98N-1265

Wockets Mgt B1 (HFA-305)
FDA
5630 Fishers Ln, Room 1061
Rockville, MD 20857-0003



20857+0003





Helen M. Ball
2330 Nashwood Drive
San Antonio, Texas 78232